

**Legislative Council
of the
Hong Kong Special Administrative Region**

**Delegation of the
Panel on Food Safety and Environmental
Hygiene**

**Report on the duty visit to study
the food regulatory systems in Japan**

15 - 21 January 2004

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List of reference materials acquired from the visit and related information which the delegation has considered in drawing up its observations

Acknowledgements

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The delegation wishes also to thank the Hong Kong Economic and Trade Office in Tokyo, and the Consul-General of Japan in the Hong Kong Special Administrative Region, for their kind assistance in drawing up the visit programme and making the logistical arrangements.

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Chapter 1

Introduction

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Figure 1 Meeting with the Honorable Naokazu Takemoto, Parliamentary Secretary for Health, Labour and Welfare, Japan



Figure 2 Dinner hosted by the Principal Hong Kong Economic and Trade Representative, Tokyo in honour of the delegation

Chapter 1 - Introduction

Purpose of report

1.1 A delegation of the Panel on Food Safety and Environmental Hygiene (FSEH Panel) of the Legislative Council (LegCo) visited Japan in January 2004 to study its food safety requirements and food regulatory systems. The report presents the main findings and observations of the delegation.

Membership of the delegation

1.2 The delegation comprises the following Members -

Hon Fred LI Wah-ming, JP (Panel Chairman and leader of delegation)

Hon NG Leung-sing

Hon CHAN Kwok-keung, JP

Hon YEUNG Yiu-chung, BBS (Panel member)

Hon LEUNG Fu-wah, MH, JP (Panel member)

Hon WONG Sing-chi

Hon Frederick FUNG Kin-kee

1.3 Mrs Constance LI, Chief Council Secretary (2) 5, accompanied the delegation on the visit.

Visit programme

1.4 The delegation visited Tokyo and Osaka of Japan from 15 to 21 January 2004. The delegation met with officers and executives of the following departments and organisations -

- (a) Ministry of Health, Labour and Welfare (MHLW)
- (b) Ministry of Agriculture, Forestry and Fishery (MAFF)
- (c) Food Safety Commission (FSC)
- (d) Osaka Prefectural Government
- (e) Kinki Regional Bureau of Health and Welfare
- (f) Chiyoda Ward Office
- (g) Narita Airport Quarantine Office

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- (h) Yokohama Imported Food Quarantine Centre
 - (i) Tokyo Central Wholesalers Market (Tsukiji Market)
 - (j) Osaka Prefecture Wholesale Market
 - (k) Aeon Group (Jusco Minamisuna Shop)
 - (l) Mitsukoshi Group (Nihonbashi Main Store)

1.5 The visit programme is in **Appendix I**. A list of the government officers, executives and other persons with whom the delegation met is in **Appendix II**.

Purpose of the visit

1.6 The FSEH Panel is tasked to monitor Government's policies and practices in setting and monitoring food safety standards for safeguarding public health. The main areas of concern of the Panel include the food surveillance and inspection systems, food regulatory framework and the proposed food labelling systems.

1.7 In 2003, the Panel decided to send a delegation to visit Australia and Japan to have a better understanding of the import and export control of food products and the food regulatory systems in these countries.

1.8 The visit to Australia was made in July 2003. Australia was selected because it is a key trading partner of Hong Kong, and it exports a significant amount of seafood, dairy produce and meat products to Hong Kong.

1.9 The visit to Japan was deferred to January 2004. Japan was selected because it is similar to Hong Kong in that it imports a great variety of food from other places, and Japan has put in place sophisticated food regulatory and food labelling systems.

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Chapter 2

Food regulatory framework in Japan

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Chapter 2 - Food regulatory framework in Japan

Organisational structure

Ministry for Health, Labour and Welfare

2.1 Following a reorganisation of ministries in January 2001, the Ministry of Health and Welfare and the Ministry of Labour were merged into the present Ministry for Health, Labour and Welfare (MHLW). Under MHLW, the Pharmaceutical and Food Safety Bureau, in particular its Department of Food Safety, is responsible for the administration of food safety. An organisation chart of MHLW is given in **Appendix III**.

2.2 The following divisions under the Department of Food Safety are responsible for food matters -

- (a) the Policy Planning and Communication Division is responsible for general coordination and risk communication. Its Office of Port Health Administration deals with all quarantine matters and inspection of imported food;
- (b) the Standards Evaluation Division is responsible for establishment of specifications/standards for food, food additives, pesticide residues, animal drug residues, food containers and food labelling. Its Office of Health Policy on Newly Developed Food sets the labelling standards and deals with safety assessment of genetically modified (GM) food; and
- (c) the Inspection and Safety Division is responsible for food inspection, health risk management, safety measures for poultry and livestock meat, and measures for environmental contamination. Its Office of Import Food Safety deals with assurance of import food safety.

Ministry of Agriculture, Forestry and Fisheries

2.3 The Ministry of Agriculture, Forestry and Fisheries (MAFF) was reorganised in January 2001 to implement effectively the measures in the Basic Law on Food, Agriculture and Rural Areas. The reorganisaton was to cope with changes in the agriculture, forestry and fisheries industries in the 21st century, in order to ensure a stable food supply for Japan, in view of its increasing reliance on imported food and decreasing food self-sufficiency ratio.

2.4 Under the reorganised MAFF, the General Food Policy Bureau is responsible for food policy and matters relating to maintaining stable food supply. The Bureau promotes domestic production of food while ensuring stable imports and stockholdings. It also provides information on healthy diets, establishes labelling systems for organic foods and GM foods, develops a robust food products industry, and promotes international cooperation in pursuit of long-term stability of the world's food supply.

Food Safety Commission

2.5 The Food Safety Commission (FSC) was established on 1 July 2003, following the enactment of the national Food Safety Basic Law in May 2003 which sets out the duties and functions of FSC. FSC is an independent organisation responsible for undertaking risk assessments on food, while MHLW and MAFF are responsible for risk management.

2.6 FSC was established in response to increasing public concern about food safety matters, such as changes in the types of foods consumed due to advances in technology, outbreaks of Bovine Spongiform Encephalopathy (BSE), O-157 E.coli infection, and the problem of pesticide residues in food.

2.7 FSC is primarily tasked to -

- (a) conduct scientific, independent risk assessments on food and make recommendations to relevant ministries;
- (b) communicate with stakeholders (i.e. consumers and food-related business operators) on food risks; and
- (c) respond to food incidents/emergencies.

2.8 FSC comprises seven commissioners who are experts on food safety issues. It holds weekly meetings which are open to the public and the media. Under FSC, there are 16 Expert Committees which carry out risk assessments and risk communication on different types of foods, and they also coordinate responses in case of food incidents.

2.9 A chart showing the working relationship among MHLW, MAFF and FSC is given in **Appendix IV**.

Food safety administration

General

2.10 The food safety administration in Japan is based on the Food Safety Basic Law, Food Sanitation Law, Abattoir Law, Poultry Slaughtering Business Control and Poultry Inspection Law, and other related laws.

2.11 The Food Safety Basic Law was enacted in May 2003 in response to the increasing concern about food safety (also see paragraph 2.14). A risk analysis approach was introduced by this legislation in that risks are scientifically assessed and expressed in terms of probability and degree of adverse health effects. Necessary measures are developed based on the risk assessment findings. The approach consists of three elements, i.e. risk assessment, risk management and risk communication. The Food Safety Basic Law mainly deals with risk assessment, while the Food Sanitation Law and other related laws deal with risk management.

2.12 Local governments play an important role in implementing risk management. Local governments issue licences to food establishments, conducts inspections to licensed establishments within their jurisdictions, carries out tests on imported food, and investigates into food incidents.

2.13 An overview of the administration of food safety is given in **Appendix V**.

Recent legislative amendments

Food Safety Basic Law

2.14 In May 2003, Japan enacted the Food Safety Basic Law to ensure food safety in order to protect public health. Article I of the Food Safety Basic Law sets out the objectives of the law, as follows -

"In consideration of the vital importance of precise response to the development of science and technology, the progress of internationalization and other changes in the environment surrounding nationals' dietary habits, the purpose of this Law is to comprehensively promote policies to ensure food safety by establishing basic principles, clarifying the responsibilities of the state, local governments and food-related business operators and the roles of consumers, and establishing a basic direction for policy formulation in regard to ensuring food safety."

An extract of the Food Safety Basic Law is in **Appendix VI**.

Food Sanitation Law

2.15 The Food Sanitation Law is concerned with risk management of food. It provides for -

- (a) specification of standards for foods, food processing facilities, food business operation and management, and food labelling; and
- (b) inspection of imported food by national government, and inspection of domestic food businesses and guidance to these businesses by local governments.

2.16 The Food Sanitation Law has been drastically amended recently to step up measures to ensure food safety. Many of the amendments have already taken effect, while some provisions will come into operation in 2004 or 2006.

2.17 The major amendments include the following -

- (a) the national and local governments must provide information on food hygiene, promote related studies and gauge public views on these matters;
- (b) food business operators including distributors have the responsibility to acquire knowledge and techniques, conduct testing and ensure safety of raw ingredients. They must retain records of raw ingredients, and investigate the cause of food poisoning incidents arising from the food they produce/sell;
- (c) a positive list system will be introduced in 2006 for pesticides, veterinary drugs and related chemicals. Under the system, domestic distribution of crops containing these substances which are not on the list will be prohibited;
- (d) MHLW will prohibit the use of certain food additives that have a safety problem. MHLW may also prohibit the distribution of newly developed foods, and foods with false or exaggerated labelling or advertising;
- (e) a registration system for laboratories (including private laboratories) is introduced for conducting tests on foods as required by examination orders of MHLW;
- (f) MHLW will publish guidelines for inspection and testing of imported foods, and local governments must also publish implementation plan for inspection and guidelines on food hygiene;

- (g) food business operators must obtain approval or renewal of approval of their HACCP plans, and they must respect the comments made by food sanitation supervisors; and
- (h) the maximum penalties for labelling offences have been raised.

Confectionery Hygienists Law

2.18 The Confectionery Hygienists Law provides for the qualifications of, and a licensing system for, confectionery hygienists. The hygienists must pass certain tests given by the prefecture governors and obtain a licence before they can produce confectionery.

Abattoir Law

2.19 The Abattoir Law regulates the operation of slaughterhouses (a total of 241 in Japan) and the processing of livestock for food purposes. No livestock intended for food use may be slaughtered or dressed in places other than a permitted slaughterhouse (also see Chapter 5).

Poultry Slaughtering Business Control and Poultry Inspection Law

2.20 Under the Poultry Slaughtering Business Control and Poultry Inspection Law, any person who wishes to slaughter fowls and remove feathers and viscera from their carcasses must obtain permission from the local government. The legislation also provides for a poultry inspection system (also see paragraphs 5.7 to 5.10).

Rendering Plants Control Law

2.21 The manufacture of leather, glue, fats/oils, fertilizers, feeds and other products using parts of livestock (including meat, skin, bones and organs) as ingredients can only be carried out in those plants permitted by the local government. Moreover, any person who wishes to raise or impound animals (including livestock and poultry) exceeding the specified number must also obtain the permission of local governments.

Law on Temporary Measure for Enhancing the Control Method of the Food Production Process

2.22 This legislation provides that MHLW and MAFF must formulate and publicize a basic policy on enhancing the management of food production process. Food manufacturers and processors may submit a plan to enhance the food production process for accreditation. Accredited manufacturers and processors may receive a long-term, low-interest loan necessary for carrying out the enhancements, and may also obtain preferential taxation.

Health Promotion Law

2.23 The Department of Food Safety of MHLW makes regulations under this law to set out the labelling requirements on nutrition information (also see paragraphs 4.5 to 4.8) and foods for specified health uses (also see paragraphs 4.3 to 4.4). The Health Services Bureau of MHLW is required to conduct national health and nutrition surveys for promoting the health of the nationals. The law also requires that dieticians must be engaged by the municipal governments and specified mass-meal production plants.

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Chapter 3

Imported food

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Figure 3 Visit to Narita Airport Quarantine Office



Figure 4 Visit to Yokohama Imported Food Quarantine Centre

Chapter 3 - Imported food

General

3.1 Japan's domestic production supplies about 40% of the country's food consumption based on calories supplied. The remaining 60% is imported from about 200 countries/places. With the increased reliance on imported food, the stable supply and the safety of imported food have become one of the priority concerns of the country.

3.2 The main legislation governing the safety of imported food is the Food Sanitation Law which is enforced by Ministry of Health, Labour and Welfare (MHLW). In April 2003, there are 31 quarantine stations and about 283 Food Sanitation Inspectors under MHLW that perform inspections on imported foods.

3.3 The delegation visited the Narita Airport Quarantine Office and the Yokohama Quarantine Station, and received briefings on the importation procedures and inspection/examination requirements for imported food.

Importation procedures

Import notification

3.4 Importers of all foods and drinks which are intended for sale in Japan must submit import notifications to the relevant MHLW quarantine station before shipment. The importer must provide information on the country of origin, the material used for packaging, and in the case of processed food, the ingredients (and food additives) and the manufacturing/processing method. Supporting documents such as hygiene certificate and result of laboratory testing on the ingredients or food additives are also required.

Examination and inspection

3.5 At the quarantine station, the Food Sanitation Inspectors carry out document examination and cargo inspection. The examination is to ensure that the imported food comply with the standards and requirements stipulated in the Food Sanitation Law. The Quarantine Station also checks against past records of non-compliance or problem consignments. If the consignment presents no problem, it will be cleared through customs and released for distribution.

3.6 For "first time" imports and imports that have a history of non-compliance with the Food Sanitation Law, the Quarantine Office may draw samples for laboratory testing. The Quarantine Office maintains lists of monitoring items in order to check, for instance, the presence of food additives, agricultural chemicals, antibiotics, toxins, bacteria, *E. coli*, *Vibrio* and GM organisms (GMO) in imported foods.

3.7 Alcoholic drinks and food-related utensils (e.g. bowls and cups) are also subject to the regulation of the Food Sanitation Law, and they are inspected at points of import to ensure that they do not contain toxic materials. Live fish imported into Japan is also checked for the presence of antibiotics. The fish will be kept in the quarantine station and will not be released for distribution pending the test results.

3.8 Japan accepts the results of tests conducted by qualified laboratories in exporting countries, and these laboratories must first be registered with MHLW. These laboratories must be capable of conducting tests using AOAC methods (i.e. methods designed by the US Association of Official Analytical Chemists) and they are mostly government or certified laboratories in the exporting country.

Examination order

3.9 Article 15 under Paragraph 3 of the Food Sanitation Law provides that examination orders may be issued for food and other related substance that are suspected of violating the law, in the light of the hygiene conditions in the exporting countries and previous records of violations. If a certain food product is subject to an examination order, it will not be allowed to enter Japan unless it has passed the examination each time.

Monitoring tests

3.10 Monitoring tests of individual food products are conducted based on scientific sampling. MHLW issues detailed lists of test items (e.g. pesticide residues, food additives and pathogenic micro-organisms), taking into account the prevailing hygiene conditions. MHLW conducts about 72 000 tests in the fiscal year 2003, an increase by 20 000 over that conducted in 2002. If the monitoring shows that certain products are in violation of the law, MHLW will increase the frequency of tests and even issue an examination order on these products.

3.11 At the Yokohama Quarantine Station, food samples collected by Food Sanitation Inspectors are tested at the laboratory in the Station. These samples undergo chemical analysis to test for food additives and residual agricultural chemicals, and also microbiological analysis for screening of *O-157* and *Salmonella*, etc.

Cases of violation of the law

3.12 If the inspection or examination results reveal that the imported food is not in compliance with the Food Sanitation Law, the consignment will be re-shipped, destroyed or otherwise treated. Other administrative measures include recall of the product concerned, revocation of licence or prohibition of all or part of the business concerned. Persons convicted of breaches of law may be imprisoned for one to three years and ordered to pay a fine of 50 000 yen to 3,000,000 yen (up to 100 million yen for a corporation).

3.13 The majority of violation cases involved non-compliance with Article 7 of the Food Sanitation Law, e.g. not meeting the specification standards for components, presence of residual agricultural chemicals and illegal use of additives in the manufacture process. These cases comprise approximately 65% and 57% respectively of violation cases processed at the Narita Airport Quarantine Office and the Yokohama Quarantine Station. In December 2001 and March 2002, certain Chinese raw vegetables were found to have problems of pesticide residues, and strengthened monitoring tests had been conducted on vegetables from China.

Facilitation of imports

3.14 To facilitate the importers in submitting the notification forms, Japan has introduced a computer-assisted system called FAINS (Food Automated Import Notification and Inspection System). Currently, about 89% of import notifications are received through this system, which is linked to the Nippon Automated Cargo Clearance System. An electronic transmission system was also established between Japan and Australia in March 1998 for transmission of health certificates of meat and meat products.

3.15 To further facilitate the import trade, importers may submit import notifications seven days before the expected arrival of the cargo. If certain types of foods are to be imported repeatedly, importers can submit an importation plan during the first shipment. If there is no hygiene problem with the food, the importers may be exempted from submitting an import notification for subsequent shipments over a specified period of time.

Exemptions

3.16 Certain types of foods which do not pose safety problems are exempted from the import notification requirement. These foods, as specified in the Food Sanitation Law, include copra, crude alcohol, crude animal and vegetable fats, raw salt, raw sugar, molasses, rape seeds, etc.

3.17 Certain food substances may be exempted from regular inspection if MHLW confirms that they comply with the Food Sanitation Law and if the manufacturing or processing plant in the exporting country has been registered with MHLW. The exemption is valid for three years, and during the exemption periods, MHLW still conducts random checks on the registered substances at points of import.

Consultation on imports

3.18 Consultation sessions were held with importers as part of the guidance programme of quarantine offices. About 1 000 visitors consulted the Yokohama Quarantine Station on food importation matters in 2002. The consultation was mainly on the food inspection programme and confirmation of the manufacture method.

Increase in workload

3.19 As Japan depends more on imported food, a larger quantity of food was imported and examined at the quarantine stations. In 2002, a total of 1 619 032 food items were imported into Japan, 135 480 inspections were conducted, and there were 917 rejected cases. Given the increase in workload and only a few additional staff had been hired, major quarantine stations in Japan had to work longer hours than before.

Examination centres

3.20 There are two central examination centres (Yokohama and Kobe) and 11 medium-size laboratories in Japan. The examination centres play a very important role in the national program on imported food inspection and control of infectious diseases from abroad.

3.21 The examination centre at the Yokohama Quarantine Station was established in 1991. Since then, its functions and responsibilities had been much expanded because of the significant increase in imported food and advance in food technology such as the GM food technology. Apart from conducting microbiological and chemical tests, the examination centre also carries out internal audits on checked samples as part of the quality assurance program. The delegation has noted that the examination centre also conducts other types of tests, e.g. the seawater quality at Yokohama to check whether there are pollutants brought in by vessels.



Chapter 4

Food labelling



Chapter 4 - Food labelling

General

4.1 The Food Sanitation Law requires that food, food additives, food apparatus and containers/packages intended for sale must be labelled with information such as contents, best-before date, manufacturer and storage methods.

Foods containing allergic substances

4.2 In April 2001, the Food Sanitation Law was amended to include provisions on labelling of foods containing allergic substances, in order to provide necessary information to customers to prevent health risk. Mandatory labelling is required for five types of foods which can cause severe allergic symptoms, i.e. eggs, milk, wheat, buckwheat and peanuts. In addition, the food trade is also encouraged to provide necessary information on the labels of 19 types of foods which can cause symptoms of allergy of a lower degree of severity. These foods include abalone, squid, salmon roes, prawn, oranges, crabs, beef, walnuts, soybeans, chicken, pork, etc.

Foods for specified health or dietary uses

4.3 Foods for specified health uses refer to all foods intended to maintain or enhance the health conditions, or for special health uses by people who wish to control health conditions such as blood pressure or level of cholesterol. Manufacture or distribution of these foods requires permission of the national government. Permission will be given after evaluation of the safety and efficiency of the health functions claimed.

4.4 Foods for special dietary uses refer to all foods intended for special dietary uses, e.g. food for the ill and aged, milk powder for pregnant women and infants, and foods for specified health uses. These foods must be labelled to the effect that they are intended for any of the special uses and that permission or approval for the food has been given. The food label must also include information as prescribed in the Ministerial Ordinance under the Health Promotion Law, e.g. name and address of manufacturer, permitted health claim, amount of nutrients, calories, ingredients, use-by date, recommended daily intake and methods of consumption/preservation.

Nutrition information

4.5 Foods with nutrition claims refer to all foods intended to supply or supplement nutrients that are liable to deficiencies in daily life. Such foods can be manufactured or distributed without specific permission from or notification to the national government, subject to their meeting the prescribed standards and labelling requirements.

4.6 Foods labelled with information on calories or nutrients (other than foods for specified health uses) must comply with the Nutrition Labelling Standards prescribed by Ministry of Health, Labour and Welfare (MHLW) in the Health Promotion Law. Information on the five core nutrients, i.e. protein, fat, carbohydrate, minerals and vitamins, must be included in these food labels. Information on these nutrients must be written in Japanese on the container or package in a manner that is easy to read. The delegation was informed that the five core nutrients were selected after a survey on the health conditions and nutrient deficiencies among the Japanese.

4.7 There are specific labelling requirements concerning description of the amount of, or the level or range of such nutrients. For example, the amount of each nutrient must be shown in terms of per 100g or 100ml, or per serving or package. A minimum or maximum level is also prescribed for claims using terms like "high" protein, "rich" in Vitamin A, "low" fat, "reduced" sodium, "containing" iron, etc.

4.8 According to MHLW officers, the food trade does not have much objection to the nutrition information labelling requirements, because not much additional costs are involved and the manufacturers also want to include such information as a marketing tactic.

4.9 The nutrition labelling standards of Japan are given in **Appendix VII**.

GM food

4.10 In April 2001, labelling of GM food also became mandatory in Japan. Ministry of Agriculture, Forestry and Fishery (MAFF) and MHLW are responsible for monitoring compliance with the GM labelling requirements. MAFF is responsible for enforcing the Japanese Agricultural Standards Law with an aim to enable customers to make informed food choices. MHLW is responsible for conducting safety assessments on GM food under the Food Sanitation Law.

4.11 As at July 2001, five crops (i.e. soybeans, corns, rape seeds, potatoes and cotton seeds) and 30 types of processed foods containing ingredients made from these crops are subject to mandatory labelling. However, voluntary labelling applies to the following processed foods -

- (a) products from which recombinant DNA and protein are removed; and
- (b) products in which the crops are not used as major ingredients (major ingredients refer to the three major ingredients of the product in terms of weight, and the proportion of each ingredient is 5% or more by weight).

4.12 Certain GM ingredients, such as Starlink corn, 55-1 papaya and New Leaf Y potato are prohibited in Japan.

4.13 According to MHLW officers, very few GM food products are imported into Japan. Although negative labelling is entirely voluntary, almost all manufacturers have labelled their non-GM food as such.

4.14 As regards adopting a 5% threshold for mandatory labelling of GM food. MHLW officers informed the delegation that Japan had taken into consideration the actual manufacture and distribution process of crops, and noted that inadvertent mixture of GM ingredients was sometimes inevitable in the process. Japan has also made reference to the situation in other countries such as the United States of America, conducted public consultation and carried out scientific analysis before deciding on the 5% threshold.

Enforcement

4.15 While MHLW is mainly responsible for setting standards, conducting safety assessment and monitoring the hygiene standard of imported food, sample checks and surveillance are carried out by the Health Inspectors under the prefecture or local governments. Foods for sale at food premises, including supermarkets, have to comply with the requirements under the Food Sanitation Law and other relevant legislation.

4.16 Where discrepancies are found in the amount of nutrients, the food business operators will be advised to rectify the discrepancies. If no improvement is made, ministerial orders may be issued, and non-compliance with the orders may lead to a fine of 500,000 yen.

4.17 As regards the sale of food beyond the "best-before" or "use-by" date, MHLW officers advised that Article 4 of the Food Sanitation Law stipulates that no person shall sell foods that are rotten, decomposed or immature, but this does not apply to food that have no adverse effects on human health and are deemed to be fit for human consumption. As a general practice, food premises are advised not to sell food beyond its expiry date. Enforcement action will be taken if the food for sale has perished and is unfit for human consumption.

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Chapter 5

Control on poultry and livestock

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Chapter 5 - Control on poultry and livestock

Livestock slaughterhouses

5.1 The Abattoir Law states that no cattle, horses, swine, sheep or goats intended for use may be slaughtered or dressed in any place other than a slaughterhouse. There are altogether 241 permitted slaughtering facilities in Japan. All livestock must be inspected by meat inspectors before it is slaughtered or dressed. There are about 2 571 meat inspectors in Japan, and they are employed by the local governments or licensed veterinarians.

5.2 Inspection at the slaughterhouses are carried out in three stages -

- (a) ante-mortem inspection
- (b) ante-dressing inspection
- (c) post-dressing inspection

Meat inspection is based on veterinary science, including microscopic examination, palpation and necropsy. Detailed examination will be conducted if the livestock is suspected of carrying any disease.

5.3 No part of the livestock including meat, viscera, blood, bones, and skin may be taken out of the slaughterhouse, or provided to any person for sale as food, before they pass the inspection.

5.4 If any livestock is found to carry diseases and is not fit for human consumption, the prefecture governors or mayors of cities may prohibit the slaughtering or dressing of the livestock or take other appropriate measures.

Poultry slaughtering

5.5 Under the Poultry Slaughtering Business Control and Poultry Inspection Law, any person who wishes to slaughter fowls (chickens, ducks, turkeys, and other fowls) and remove the feathers and viscera from their carcasses, must obtain permission from the local government. There are a total of 3 287 permitted facilities and 2 642 poultry inspectors in Japan. The poultry processing plant must meet the prescribed structural requirements, facilities standards and hygiene management standards.

5.6 The law does not allow any person other than the permitted person to operate a poultry processing plant. A licensed hygiene manager must also be employed and stationed at each poultry processing plant.

5.7 Poultry inspection are carried out in three stages -

- (a) ante-mortem inspection;
- (b) inspection of carcass surface after feather-removal and before evisceration; and
- (c) post-evisceration inspection (the inside of the carcass and the viscera are checked).

5.8 Poultry inspection may be carried out by the local government or authorised organisations/personnel. There are about 17 authorised poultry inspection organisations in Japan.

5.9 No carcasses, eviscerated carcasses, meat or other parts may be taken out of the poultry processing plant, or provided to any person for sale as food, without passing inspection.

5.10 If a fowl is found to be infected by a disease that can also infect humans, or if a fowl is found to be in abnormal conditions, all of the fowl or the abnormal parts are removed. The local government may also prohibit all poultry processing in the plant or take other appropriate actions.

5.11 The delegation has noted that no live poultry or whole chicken (fresh or chilled) is sold in retail markets in Japan. All poultry meat is cut and packaged according to the different parts before distribution to the retail markets.

Measures taken to prevent the spread of Bovine Spongiform Encephalopathy

5.12 Since 1996, there have been increasing test results suggesting that "mad cow disease" may be associated with Bovine Spongiform Encephalopathy (BSE) infection, although to date there is still no conclusive evidence that BSE will directly infect human.

5.13 As a preventive measure, Japan has since 1996 recommended related business to refrain from importing beef, bovine offal and their products produced in the United Kingdom which has a high incidence rate of BSE infection. In February 2001, Japan amended the Ministerial Ordinance to ban the importation of beef, cattle offal and their meat products from countries with occurrence of BSE (i.e. European Union countries, Switzerland, Liechtenstein, Czech, Slovakia, Slovenia, Poland, Israel and Canada) to prevent the spread of the disease into Japan.

5.14 Apart from import control, Japan amended the Enforcement Regulation under the Abattoir Law to regulate local cattle meat. BSE is added to the list of target diseases to be covered by regular surveillance and inspection. In October 2001, the Ministry of Health, Labour and Welfare (MHLW) established a system to ensure that beef and related products derived from infected animals will not enter the food chain. Under the system, BSE screening tests are conducted on all food animals, and there is a mandatory requirement to remove and incinerate the skull, spinal cord and end of the intestine tenure obtained during meat processing.

5.15 MHLW has also requested food manufacturers and processors to monitor those food with bovine-based ingredients. The trade is advised not to use such ingredients for food processing, and to suspend the sale of or recall those food products using ingredients of the risk category.

5.16 In addition, MHLW encourages the use of a new carcass treatment method, i.e. the spinal cord is removed before halving, to minimize the contamination of a pre-washed carcass with the spinal cord protein.

5.17 A Special Measures Law was passed in June 2002 to establish a system to ensure a stable supply of safe beef, and prevent the occurrence and spread of BSE in Japan. As required under the law, the Ministry of Agriculture, Forestry and Fishery (MAFF) and MHLW have drawn up contingency measures to be taken by the national and local governments in the event that there is a suspected or confirmed BSE case.

Measures taken to control the spread of Avian Influenza

5.18 Just before the delegation arrived in Japan on 15 January 2004, there was an outbreak of H5 Avian Influenza in a chicken farm in Tokyo, following a series of outbreaks in neighbouring countries such as Vietnam and South Korea. The Avian Influenza outbreak in Japan occurred in one layer flock in a farm in Yamaguchi Prefecture. It was reported that about 6 000 chickens were found dead on the farm, subsequently all 30 000 chickens on the farm were killed.

5.19 MAFF officers informed the delegation that it was already 79 years since the first outbreak of Avian Influenza in Japan in 1925. Japan therefore did not have much experience in dealing with the disease. On 11 January 2004, the local government was notified of an unusual number of chicken deaths in a chicken farm in Yamaguchi Prefecture. It was found that these chickens were infected with H5 virus. The blood test results on 13 January 2004 also confirmed that it was the same H5N1 virus as that in Vietnam and South Korea. However, it was uncertain whether the H5 virus was imported from migratory birds.

5.20 MAFF had immediately strengthened DNA tests and surveillance on chickens in farms and investigated the reasons for the outbreak including the route of migratory birds. In addition, the following measures had been taken to control the outbreak -

- (a) all chickens in the affected farm were killed and thorough cleansing and disinfection were carried out for the affected farm. Enhanced biosecurity measures were also taken to prevent entry of wild birds, animals and insects into the farm;
- (b) movement of poultry, poultry products, and articles from farms within a radius of 30 kilometres of the affected farm was prohibited for at least 28 days;
- (c) random check and screening of all poultry were carried out within the restricted movement area for at least 28 days; and
- (d) the farms within the restricted movement area would be placed under monitoring for three months after the 28 days.

5.21 A monitoring and surveillance system was implemented in Japan to facilitate early detection of H5N1 infection cases in farms. Operators of poultry farms had to notify the local governments of any unusual deaths of chickens in their farms. The local government also conducted sample checks on the chickens, and clinical tests were conducted on doubtful cases. MAFF officers informed the delegation that Japan adopted the strategy of massive cull, and not vaccination of chicken, in addressing the avian flu problem, because vaccination was costly and its effectiveness had yet to be established. The permission of the national government would be required if a vaccination programme for chickens was to be introduced in Japan.

5.22 The delegation noted that the massive cull of chickens was carried out by the affected farm(s) themselves with some assistance by the local government, and no compensation was paid to the farmers/operators concerned. The local government provided land and subsidies for the incineration and burying of the culled chickens. A non-guaranteed low-interest loan was available to farmers.

5.23 The delegation was informed that although there had not been any case of human infection through consumption of chicken or eggs, Japan had stopped exporting its poultry meat and eggs to other countries. Similarly, Japan had banned the import of all poultry meat and poultry products from countries with H5N1 cases. The quarantine officers in Japan also had to undergo health checks as a precautionary measure.

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Chapter 6

Wholesale and retail markets

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Figure 5 Visit to Tokyo Central Wholesale Market (Tsukiji Market)



Figure 6 Visit to Osaka Central Wholesale Market



Figure 7 Visit to a supermarket in Tokyo

Chapter 6 - Wholesale and retail markets

Wholesale markets

6.1 The delegation visited the Tokyo Metropolitan Central Wholesale Market in Tsukiji and the Osaka Prefecture Central Wholesale Market.

Tokyo Metropolitan Central Wholesale Market in Tsukiji

6.2 The Tokyo metropolitan government has established 11 central wholesale markets, in order to ensure that fresh foods are delivered promptly to customers, and are safe to eat and reasonably priced. The Tokyo metropolitan government is responsible for the construction of the market, and maintenance and management of the facilities. Supervisors employed by the Tokyo metropolitan government inspect the markets daily to give directions and supervise the handling of food in the markets, and conduct bacteriological examinations on the food. If any violation of the Food Sanitation Law or harmful food is found, the supervisors can take administrative action to dispose of the food or prohibit the sale of the food.

6.3 According to the Tokyo metropolitan government officials, Tsukiji Central Wholesale Market, which was constructed in 1935, is the largest fish wholesale market in the world, with over 450 marine products and 350 farm products (vegetables and fruits) for sale in the market. It is also the largest wholesale market in Tokyo in terms of business turnover. About 15,000 trucks and 50 000 traders entered this wholesale market each day, and the annual trade volume is over 23 million tons. As the market building is very old and the facilities cannot cope with present day requirements, there are plans to relocate the market to the seafront in 10 years' time.

6.4 Apart from the market place for auction and distribution of marine and farm products, Tsukiji Central Wholesale Market also comprises shops of the intermediary wholesalers and allied traders, restaurants, community facilities (such as bank, clinic, post office), and the Sanitation Inspection Station.

6.5 There are 270 auction days a year in Tsukiji Central Wholesale Market. The auction of fish starts at 4:40 am, and that for vegetables and fruits start at 6:30 am and 7 am respectively. The produce and supplies from all over the country and from abroad are gathered and brought into the market from 3 pm and throughout midnight for auction early next morning. Only authorised wholesalers, intermediary wholesalers and buyers can take part in the auctions. Although there is no legislation requiring that producers must sell their produce to the central wholesale markets, most produce are traded at the wholesale

markets through the local purchase brokers, because of better facilities in the wholesale markets and the large business turnover of wholesale markets.

6.6 All produces sent to the central wholesale markets are sold by open auction. Under the municipal ordinance, the commission of the wholesalers are set at 5.5% of the wholesale price for seafood, 8.5% for vegetables, 7% for fruit, 9.5% for flowers and 3.5% for meat.

Osaka Prefecture Central Wholesale Market

6.7 The Central Wholesale Market was established by the Osaka Prefectural Government in 1978 to cope with changes in the distribution of perishable foods, and to maintain stable prices and efficient distribution of such foods. Its operation is regulated by the Wholesale Market Law and the Osaka Prefectural Government Market Operation Ordinance. The Market was located in Ibaraki City, the centre of northern Osaka, in view of the rapid urbanisation and substantial increase in population in that area.

6.8 Since its establishment, the Market has been expanded and upgraded to provide low temperature storage facilities and refrigerated warehouses to maintain freshness of foods, and Styroform disposal area to reduce the amount of garbage.

6.9 A wide variety of foods, including fresh and chilled marine products, vegetables, fruits and processed foods, are traded through the Osaka Prefecture Central Wholesale Market. Like other central wholesale markets in Japan, all foods sent to this Market are sold by auction. Its business turnover in 2002 was about 350 000 tons or 124,232 million yen.

6.10 The Market is financed by auction commission (0.25% of wholesale price), shop rental, and subsidies from the Osaka Prefectural Government. It employs 47 staff, including 14 part-time staff, mainly for market operation and management.

Market Sanitation Inspection Station

6.11 Sanitation supervisors are employed by the local government to supervise and advise on the sanitary conditions of foods sold in the wholesale markets. They conduct inspections and take food samples for examination prior to auction. A laboratory is usually attached to the central wholesale market to enable quick testing of food samples.

6.12 Early every morning, the sanitation supervisors tour round the market and go from shop to shop to ensure that the food is not placed on the floor and is handled in a hygienic manner. They also give guidance on the handling of food during inspection. Inspection of food is focussed on three areas -

- (a) whether there are bacteria and harmful substances (e.g. food additives, mercury and pesticides above limits) in the food;
- (b) whether the food is kept under the required temperature; and
- (c) whether the food labelling requirements are complied with.

6.13 Where meat or fish processing is carried out in a central wholesale market, the whole process from slaughtering to dressing and cuts is placed under strict supervision. All personnel and visitors must wear protective garments and boots, and go through the disinfection process before they are allowed to enter the works area.

6.14 If breaches of the Food Sanitation Law are found, the Market management will trace the source of the food. Where appropriate, the local government may order food recall or suspension of sale of the food, or impose a fine on the producer concerned. The local government of the place of manufacturer or producer will also be alerted to ensure no recurrence of breaches. In most cases, only administrative actions are taken against breaches of the Food Sanitation Law, and prosecution has been taken in a few cases.

6.15 According to the sanitation supervisors, temperature management is the most important in controlling the growth of bacteria in food. Specific checks are also conducted on certain foods (such as oysters) in summer in view of the higher incidence of gastro-enteritis in hot season.

6.16 The Market Sanitation Station also organises training courses and seminars for traders and operators to enhance the sanitary conditions in food handling.

Retail markets/supermarkets

6.17 The delegation visited a supermarket each of the Aeon Group (Jusco) and the Mitsukoshi Group.

6.18 According to the supermarket management, no live chicken or whole chicken is sold at retail markets and supermarkets in Japan. While most food items are packaged for sale, some live seafood, which are kept in natural seawater, is sold in a few supermarkets.

6.19 Inspection of food, especially fresh foods such as fish (for sashimi purpose), meat, vegetables and fruits, is carried out every day by management staff. Reports are made to the headquarters twice a month on improvements required. The supermarket management stresses the importance of temperature management because higher temperature is favourable to bacteria growth. Food handlers and supermarket staff are also required to pay attention to their health conditions and personal hygiene.

6.20 The supermarket management impressed upon the delegation that they gave much emphasis on providing customers with more information to facilitate them to make informed choices. In addition, "use by" dates must be shown on all food labels. For fish slices used for sashimi purpose, the use-by period is only one day and any unsold stock by the end of the day has to be disposed of. In addition to the usual customer complaints mechanism and food recall procedures, the Aeon Group management said that they would also inform the public if any of the food items sold in its supermarkets was found to be sub-standard or unsafe.

6.21 According to the Aeon Group management, MAFF and MHLW did not make prompt responses when a BSE case was confirmed in Japan in September 2001, and this had caused much confusion and public concern. To restore consumer confidence in the safety of beef, a record tracing system has been introduced by Aeon Group for beef sold in its supermarkets. All cattle kept in the Tasmanian farm owned by the Aeon Group are embossed with identification numbers. After slaughtering, the beef are packed into boxes bearing the relevant identification number for distribution to supermarkets. The identification number and other information are shown on the package of the beef, and customers can check the information from the computerised record tracing system installed at the supermarket. Through the system, customers can trace the records on cattle raising, production process, inspection/certification process and the distribution of end-products.

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Chapter 7

Regulation of food business

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Figure 8 Meeting with officials of the Osaka Prefectural Government

Chapter 7 - Regulation of food business

General

7.1 The delegation was briefed by the Osaka Prefectural Government on the regulatory framework for food business in Osaka.

7.2 The Osaka Prefecture, located at approximately the centre of Japan, is divided into 33 cities, 10 towns and one village. Osaka has an area of approximately 1,890 square kilometres (0.5% of the country's total land area), and is the second smallest prefecture. However, it has a population of 8.8 million, or 7% of the entire population of Japan, making it the second most populous prefecture after Tokyo.

7.3 According to the Osaka Prefecture officials, its Food Sanitation Law was revised in 2001 to strengthen control over the safety of imported food, mainly to address concerns about unapproved food additives and agricultural pesticide residue in food. In this respect, prefecture governments follow the advice and standards of the national government which regularly conducts citizen health surveys and risk assessments on foods.

Food business licensing

7.4 The licensing requirements for food businesses are set out in the Food Sanitation Law. Under the law, all food businesses must obtain permission of the local governments before they are allowed to operate. These include snack shops, food factories, meat processing plants, restaurants and shops selling dairy products, seafood, ice-cream and frozen confectionery, etc. For those food premises which handle puffer fish (雞泡魚), the operator must also obtain a licence from the national government in addition to a local government licence.

7.5 Food premises must comply with the specific requirements stipulated in the law concerning the general and food preparation facilities, food handling and food storage equipment, water supply and sewage systems, and hygiene requirements for food handlers, etc. The Food Sanitation Law of Osaka also stipulates hygiene requirements such as daily cleansing and disinfection of toilets, provision of washing basin and liquid soap for food handlers, refrigerated storage facilities with a temperature below 10°C, and annual inspection of water supply and sewage systems, etc.

7.6 The delegation has noted that while there are legal provisions on the hygiene standards of water used for cooking, no similar provisions exist for the water used for keeping live seafood. However, it is the common understanding and practice among food operators that live seafood for sashimi purpose must be kept in hygienic artificial seawater or disinfected seawater. As regards water for washing iced fish or meat, drinkable water has to be used. The Osaka Prefectural Government also requires that if a food operator wishes to use water other than that from the mains supply, he/she must obtain permission from the licensing authority which will specify the cleansing and disinfection requirements of the water supply and storage facilities.

7.7 The average time for issuing a food business licence by Osaka Prefectural Government is about 15 days, while that issued by the national government is about 30 days. In addition to the food business licence issued by the Food Sanitation Department (保健所) of the local government, the food premises must separately apply for permission from the Fire Services and Building Departments regarding the fire and building safety of the premises. For businesses which involve processing of meat, dairy products or food additives, the responsible person must have the necessary qualifications (such as dieticians or chefs) or attended recognised courses organised by the Food Sanitation Department.

Inspection of food premises

7.8 According to the Osaka Prefectural Government officials, licensed food premises are inspected a few times a year despite the general requirement that monthly inspections should be paid. A warning or advice will be issued for minor breaches of the licensing requirements. However, repeated or serious breaches can lead to suspension or revocation of licence.

7.9 For those food premises with outstanding hygiene standards (which represent less than 10 % of the licensed food premises), the local government will issue a certificate to them for display in the premises.

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Chapter 8

Cigarette butt littering legislation in Chiyoda Ward

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Figure 9 No-smoking sign painted on the road surface in Chiyoda Ward



Figure 10 Presentation of souvenir to representative of Chiyoda Ward

Chapter 8 - Cigarette butt littering legislation in Chiyoda Ward

General

8.1 The delegation received a briefing from the Chiyoda Ward officials on the implementation of its cigarette butt littering legislation in the municipality.

8.2 Chiyoda Ward is situated in Tokyo. It has an area of 11.64 square kilometres and a population of about 41 000 persons. However, there are about one million people working or attending school within the boundary of Chiyoda Ward during daytime.

8.3 Cigarette butt littering legislation was introduced in Japan in the 1990s. The first of its kind was enacted in Kitano Village of Fukuoka Prefecture in October 1992. As part of the tobacco control policy, local governments have taken actions to actively define non-smoking areas and launch public health campaigns against smoking. Nevertheless, the cigarette butt littering legislation in many local municipalities do not include any provision on fines or penalty, and little results have been achieved in this respect.

Outdoor smoking ban in Chiyoda Ward

8.4 The cigarette butt littering legislation originally enacted by Chiyoda Ward in 1999 did not include any penalty or fine provisions. The municipal government distributed portable ash trays to passengers at mass transit railway stations and bus stations, and increased the frequency of street cleansing. However, no significant improvement was observed after implementation of these measures.

8.5 In June 2002, Chiyoda Ward announced a new cigarette butt littering legislation with penalty provisions, which has been put into effect since October 2002. Under the new law, smoking on the road within the no-smoking area is an offence punishable by a fixed penalty of 2,000 yen, or a maximum fine of 20,000 yen. The same applies to other littering offences.

8.6 To implement the new law, clear signs are painted on the road surface to show that it is a no-smoking area. Over 3,000 no-smoking signboards are also posted along the roads. Publicity materials on the new law are distributed to companies and schools. In addition, a monitoring unit has been set up in each of the nine areas in Chiyoda Ward to monitor the situation in their respective areas. It is estimated that about 120 million yen has been spent on publicity and public education.

8.7 About 10 staff in uniform, many of them were ex-police officers, are engaged to carry out enforcement action. In addition, about 400 people, including members of the municipal government, carry out street patrol to assist in the enforcement.

8.8 A survey has been carried out by the Chiyoda Ward Office recently to evaluate the effectiveness of the new legislation. According to the survey findings, there has been marked improvement in the problem of cigarette butt littering in the area. The number of cigarette butt found in the streets has been reduced by 90% after the legislation has been put into operation.

8.9 The Chiyoda Ward Office informed the delegation that there had not been much controversy over the current level of fixed penalty. A total of 6 396 fixed penalty notices were issued during the period from November 2002 to December 2003. The enforcement staff had not encountered any violent resistance in issuing the fixed penalty tickets and collecting the fixed penalty. Over 83% of offenders paid the fixed penalty, and the majority paid on the spot. According to the enforcement statistics, 99% of the offenders were not residents of Chiyoda Ward.

8.10 In view of the success in the implementation of the new legislation, the municipality is considering extending the no-smoking areas (now 40% of the total area) to other areas in the municipality. The Chiyoda Ward Office will consult the local residents on the future plans and will make efforts to reduce the number of payment default cases.

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Chapter 9

Observations

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Chapter 9 - Observations

General

9.1 The delegation is of the view that the information collected from the visit in relation to food safety measures and food regulatory systems has provided useful reference for Hong Kong. The observations of the delegation are given in the following paragraphs.

Organisational and legislative changes

9.2 Reorganisation of ministries and legislative changes have taken place in Japan recently to enhance its administration of food safety, in response to increasing concern in Japan about new foods and food issues such as Bovine Spongiform Encephalopathy (BSE) and presence of pesticide residue in food. A new approach was adopted in 2003 by enacting the Food Safety Basic Law which introduced a risk analysis approach and stipulated the responsibilities of the state, local governments and food-related business operators in food safety matters (paragraphs 2.11 and 2.14). A Food Safety Commission was established in the same year to conduct independent risk assessments of different kinds of food and make recommendations to the relevant ministries (paragraphs 2.5 to 2.8).

9.3 The delegation has noted that the Food Sanitation Law of Japan, which deals with risk management of food, has also been drastically amended to step up measures to ensure food safety. These amendments set out clearly the responsibilities of national/local government and food operators, prohibit the use of certain food additives, pesticides, veterinary drugs and chemicals in crops and foods, establish a registration system for laboratories for food testing, and raise the maximum penalties of labelling offences, etc (paragraphs 2.15 to 2.17).

Import control

9.4 It is observed that Japan attaches great importance to food safety, particularly the safety of imported food given its dependence on imported food. Japan has put in place stringent control measures and has adopted advance laboratory testing technology, to ensure the safety of imported food, drinks and food-related utensils.

9.5 Much emphasis is placed on the testing of presence of food additives, pesticide residues, antibiotics and bacteria in both fresh and processed foods intended for sale in Japan (paragraphs 3.10 and 3.13). The provision of

examination centres/laboratories at major quarantine stations has enabled quick testing to be conducted on food samples drawn from the consignments (paragraphs 3.11 and 3.21). It has also facilitated early decisions to be taken on the release or withholding of a consignment, and early actions on food recall or suspension of similar imports as necessary.

Food labelling

9.6 The delegation has noted that food labels in Japan provide very comprehensive information on the ingredients and their quantities. There are also detailed guidelines and standards on food labelling such as those related to nutrition claims (paragraphs 4.5 to 4.8 and Appendix VII). According to government officials in Japan, the five core nutrients subject to mandatory labelling were selected after a survey on the health conditions and nutrient deficiencies among the nationals in Japan. There was not much controversy over the labelling requirement on nutrition claims because not much additional costs for nutrition information labelling were involved, and the food industry in Japan also wanted to include such information as a marketing tactic (paragraph 4.8).

9.7 Labelling of GM food is mandatory (subject to certain exemptions) in Japan. The 5% threshold is adopted by Japan having regard to its own situation and overseas experience, and after scientific research and public consultation. There are very few GM food for sale in Japan, and almost all non-GM foods are so labelled although negative labelling (i.e. non-GM food labelling) is entirely voluntary (paragraphs 4.10 to 4.14).

Regulation of poultry and livestock

9.8 In Japan, the slaughtering of livestock and poultry must be carried out at licensed/permitted slaughterhouses or poultry processing plants. The slaughtering process is subject to inspection by the meat or health inspectors (paragraphs 5.1 to 5.10). The delegation has been informed that no live poultry or whole chicken (fresh or chilled) is sold in retail markets, and the poultry meat are cut and packaged according to the different parts, before distribution to the retail markets (paragraph 5.11).

9.9 The delegation has noted that Japan adopts the strategy of massive cull of poultry, and not vaccination, in addressing the avian flu problem (paragraph 5.21). The massive cull is carried out by the farmer(s) concerned, while the local government provides assistance in finding land for the incineration and burial of the culled chickens (paragraph 5.22).

Markets

9.10 The delegation is impressed by the large trade volume and wide range of foods and facilities in the wholesale markets visited. Apart from the market place for auction and distribution of foods, Tsukiji Central Wholesale Market also comprises shops of the intermediary wholesalers and allied trades, as well as community facilities such as banks and clinics. In addition, the Market Sanitation Inspection Station and laboratory facilities are also attached to major wholesale markets to facilitate on-site inspection and quick laboratory testing on food items (paragraphs 6.4 and 6.11).

9.11 The delegation has also noted that while the wholesale markets are mainly financed by shop rental and auction commission, they also receive subsidies from local governments (paragraph 6.10).

Temperature management of food

9.12 During the visit of the delegation, the market management as well as government officials responsible for food regulation have stressed the importance of temperature management in food handling (paragraphs 6.15, 6.19 and 7.5). The delegation has the impression that the food trade is well aware of the need to keep their foods, especially the fresh foods, under the prescribed temperatures, in order to reduce the risks of bacteria growth. It is noted that special refrigerating facilities are installed at food premises for the storage of fresh foods, and the management regularly checks the temperature of the food for sale at their premises.

Conclusion

9.13 The delegation has found the visit to Japan very enlightening and useful. The detailed briefings and frank exchanges of views between the delegation and the officials and executives met in Japan have provided very good materials for further thoughts on enhancing food safety in Hong Kong.

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Legislative Council
Panel on Food Safety and Environmental Hygiene

Visit programme
 (15-20 January 2004 in Tokyo, 20-21 January 2004 in Osaka)

Date/Time	Event
<u>15 January 2004 (Thursday)</u>	
10:20 am	Depart from Hong Kong
3:25 pm	Arrive at Narita International Airport
4:20 pm - 5:20 pm	Visit to the Narita Airport Quarantine Office Briefing by Mr Naoki Hashihata, Director, on the inspection system, document requirement, on-line application, and inspection of storage space of imported food.
5:30 pm	Depart for hotel
7:00 pm	Check in hotel
<u>16 January 2004 (Friday)</u>	
9:10 am	Depart hotel
9:30 am - 10:45 am	Courtesy call on Hon. Naokazu Takemoto, Parliamentary Secretary for Health, Labour and Welfare (HLW) Briefing by officials, Ministry of HLW <ul style="list-style-type: none"> - Recent revision of the Food Sanitation Law - Setting of guideline/standard - Security of genetically modified food, and its labelling - Regulation on labelling of nutrition information

Date/Time	Event
11:00 am - 12:00 noon	Visit to Ministry of Agriculture, Forestry & Fisheries (MAFF) Received by Ms Masako Kurimoto, Director, Animal Health and Animal Products Safety Division, MAFF Briefing on regulation and hygiene requirements for poultry farms by Mr Norio Kumagai, Deputy Director, and Mr Taisumi Okura
12:30 pm - 1:35 pm	Lunch
1:40 pm	Depart Tokyo for Yokohama
3:00 pm - 5:00 pm	Visit to the Yokohama Imported Food Quarantine Center Inspection of the testing for genetically modified food, food additive, and agriculture chemicals
6:30 pm	Return to hotel
7:00 pm - 9:00 pm	Dinner hosted by the delegation

17 January 2004 (Saturday)

8:50 am	Depart hotel
9:30 am - 11:30 am	Visit the JUSCO Minamisuna Shop, supermarket of AEON Group Co. <ul style="list-style-type: none"> - Received by Mr. Tatsuichi Yamaguchi, Senior Vice President, Asia Operations, Aeon Co. followed by briefing on the AEON management of food safety - Tour round the shop - Q&A session

Date/Time	Event
12:00 noon	Lunch
2:00 pm - 3:30 pm	Visit to Mitsukoshi Supermarket at Nihonbashi Main Store <ul style="list-style-type: none"> - storage, packaging and labelling of fresh food, chilled/frozen food/pre-packaged food - food safety management
<u>19 January 2004 (Monday)</u>	
5:00 am	Depart hotel
5:30 am - 8:00 am	Visit Tokyo Central Wholesale Market (Tsukiji Market) <ul style="list-style-type: none"> 5:30-7:00 am – Tour round the market 7:00-8:00 am – Briefing on market operation and Market Sanitation Inspection, Q&A
2:30 pm - 4:00 pm	Visit to Chiyoda Ward Office <ul style="list-style-type: none"> - Briefing on the enforcement action against littering and environmental hygiene offences, e.g. littering cigarette on the road
4:30 pm - 6:00 pm	Call on the Food Safety Commission (FSC), the Cabinet Office, Japanese Government <ul style="list-style-type: none"> - Briefing on the function of the FSC
6:30 pm	Arrive at hotel
7:00 pm	Dinner hosted by Principal Hong Kong Economic and Trade Representative, Tokyo

Date/Time	Event
<u>20 January 2004 (Tuesday)</u>	
8:20 am	Depart hotel for Tokyo Station
9:13 am	Leave Tokyo Station for Osaka
11:49 am	Arrive at Shin Osaka Station
12:20 pm	Check in hotel
12:30 pm - 1:00 pm	Lunch
1:15 pm	Depart hotel
1:30 pm - 3:00 pm	Visit to Osaka Prefectural Government <ul style="list-style-type: none"> - Received by Mr. Teruo Danno, Director, Food Safety Promotion Division, Department of Public Health and Welfare - Briefing by Mr. Toshimi Hata, on the food business licensing system and the measures taken by Osaka Prefectural Govt.
3:00 pm	Depart for Kinki Bureau, Ministry of HLW
3:15 pm - 5:00 pm	Courtesy call on Director General, Kinki Bureau, Ministry of HLW Followed by the briefing by Mr. Akihiro Minami, Director, Food Sanitation Division, Kinki Bureau, <ol style="list-style-type: none"> 1) Hazard Analysis Critical Control Point (HACCP) system 2) Sashimi for export 3) Legal requirement for the poultry processing plant 4) Q & A
5:20 pm	Arrive at hotel

Date/Time	Event
<u>21 January 2004 (Wednesday)</u>	
8:00 am	Depart hotel
9:30 am - 12:00 noon	Visit to the Osaka Prefecture Wholesale Market
	- Received by Mr. Tetsuzou Makino, Director Sanitation Inspection Station, OPWM
	- Courtesy call on Mr. Masayuki Otsuki, Director-General
	- Briefing on the outline of the Market
	- Tour around the market facility
	- Site visit to Fish Process Station
	- Site visit to Sanitation Inspection Station
	- Q&A at the Sanitation Inspection Station
	Return to hotel
3:30 pm	Leave for Kansai International Airport
6:20 pm	Leave Osaka for Hong Kong

代表團在日本會晤的官員及其他人士的名單
List of officers and other persons with
whom the delegation met in Japan

厚生勞動省

Ministry of Health, Labour and Welfare (MHLW)

竹本直一 Hon Naokazu TAKEMOTO	厚生勞動省大臣政務官 Parliamentary Secretary of the Ministry of Health, Labour and Welfare
遠藤明 Dr Akira ENDOU	厚生勞動省醫藥食品局食品安全部長 Director-General, Department of Food Safety, Pharmaceutical and Food Safety Bureau Ministry of Health, Labour and Welfare (Briefer of MHLW)
長谷川真一 Mr Shinchichi HASEGAWA	厚生勞動省總括審議官(國際担当) Assistant Minister for International Affairs, Ministry of Health, Labour and Welfare
南俊作 Mr Shunsaku MINAMI, D.V.M.	厚生勞動省醫藥食品局食品安全部 監視安全課課長 Director, Inspection and Safety Division Food Safety Department, Ministry of Health, Labour and Welfare
皆川尚史 Mr Takashi MINAGAWA	厚生勞動省大臣官房國際課長 Deputy Director-General for International Affairs, Minister's Secretariat, Ministry of Health, Labour and Welfare
中村泰久 Dr Yasuhisa NAKAMURA, MD, MPH	厚生勞動省醫藥食品局食品安全部 基準審査課課長補佐 Deputy Director, Standards and Evaluation Division, Department of Food Safety, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare

磯貝達裕
Dr Tatsuhiko ISOGAI

厚生労働省醫藥食品局食品安全部
監視安全課輸入食品安全対策室室長補佐
Deputy Director, Inspection and Safety Division,
Food Safety Department, Ministry of Health,
Labour and Welfare

田中弘之
Mr TANAKA Hiroyuki

厚生労働省醫藥食品局食品安全部
基準審査課新開発食品保健対策室衛生専門官
Assistant Director, Office of Health Policy on
Newly Developed Food, Standards and Evaluation
Division, Department of Food Safety,
Pharmaceutical and Food Safety Bureau, Ministry
of Health, Labour and Welfare

小幡篤志
Mr Atsushi OBATA

厚生労働省醫藥食品局食品安全部
企畫情報課企畫法令係長
Section Chief, Policy Planning and
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Safety, Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare

熊谷優子
Ms Yuko KUMAGAI

厚生労働省大臣官房國際課企畫室
衛生専門官
Assistand Director, International Affairs Division
Minister's Secretariat, Ministry of Health, Labour
and Welfare

農林水産省

Ministry of Agriculture, Forestry and Fishery (MAFF)

栗本まさ子
Ms Masako KURIMOTO, D.V.M.

農林水産省消費・安全局衛生管理課長
Director, Animal Health Division, Consumer and
Food Safety Bureau, Ministry of Agriculture,
Forestry and Fisheries

熊谷法夫
Dr Norio KUMAGAI

農林水産省消費・安全局衛生管理課
保健衛生班担擋
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Organisational Structure of Ministry of Health, Labour and Welfare



NEW MEASURES FOR "FOOD SAFETY"

~RISK ANALYSIS~

RISK ASSESSMENT

Food Safety Commission

- To conduct risk assessment
- To recommend that agencies in charge of risk management take the necessary measures for food safety based on the results of risk assessment
- To monitor the activities of the risk management agencies
- To collect and analyze the domestic and international information on food safety hazard
- To manage risk communication by the food safety related agencies etc.

Food Safety Basic Law

RISK MANAGEMENT

MHLW

- Quarantine Stations
- Regional Bureaus of Health and Welfare
- Health Centers, etc.

**Risk management
for food safety**

Food Sanitation Law, etc.

MAFF

- Regional Agricultural Administration Offices
- Centers for Food Quality, Labeling and Consumer Services, etc.

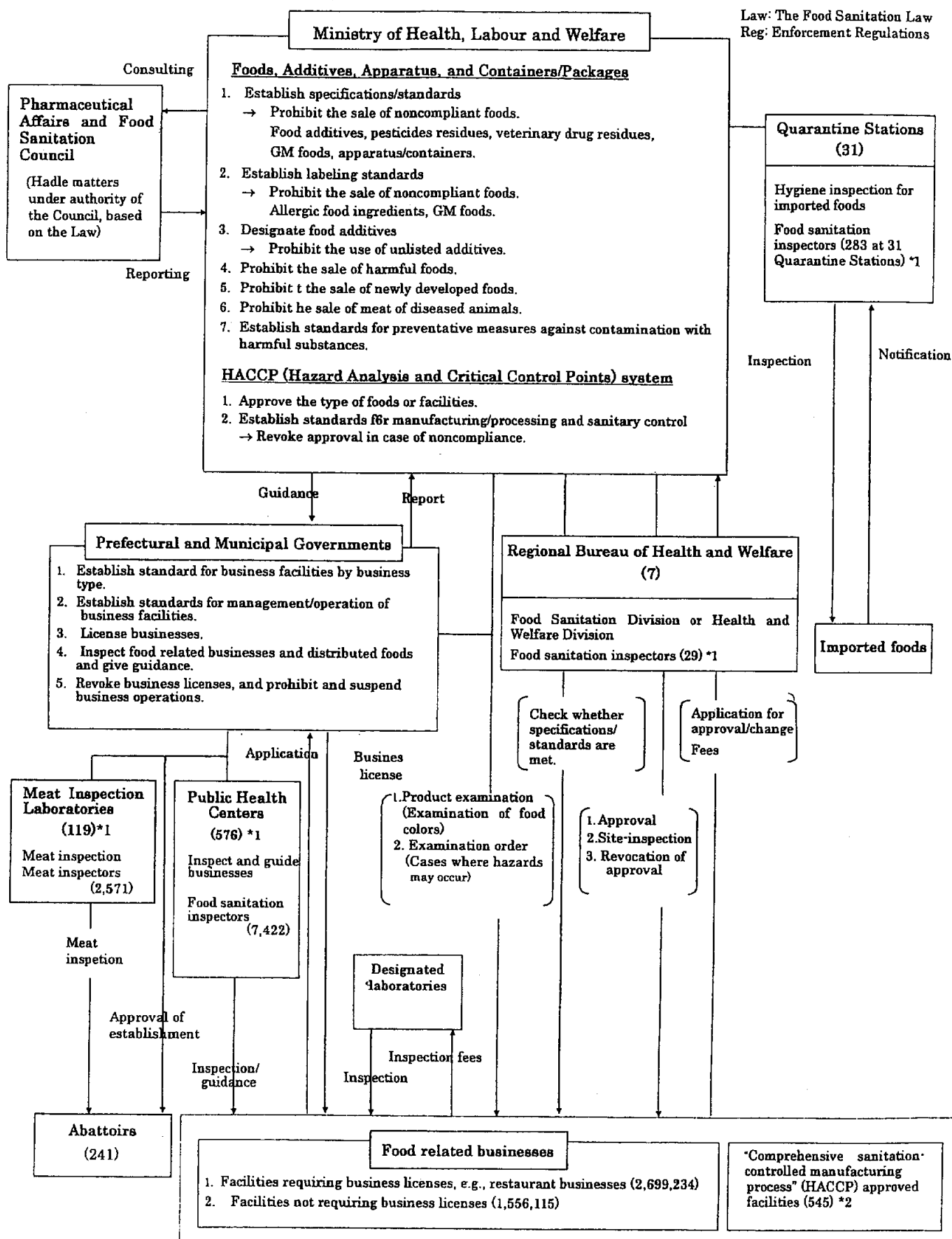
**Risk management
for agricultural
production, livestock
and fishery**

Agricultural Chemicals
Regulation Law, etc.

RISK COMMUNICATION

- Disclosure of information on food safety
- Securing opportunities to express opinions by the consumers

Overview of Administration of Food Safety



Note: The statistics are as of the end of 2001, excluding ones marked with *1 and *2.

*1 is as of April 2003, and *2 as of the end of July 2003, respectively.

The Food Safety Basic Law (Tentative Translation)

Contents

Chapter I	General Provisions (Articles 1-10)
Chapter II	Basic Direction for Policy Formulation (Articles 11-21)
Chapter III	Food Safety Commission (Articles 22-38)

Chapter I General Provisions

(Purpose)

Article 1

In consideration of the vital importance of precise response to the development of science and technology, the progress of internationalization and other changes in the environment surrounding nationals' dietary habits, the purpose of this Law is to comprehensively promote policies to ensure food safety by establishing basic principles, clarifying the responsibilities of the state, local governments and food-related business operators and the roles of consumers, and establishing a basic direction for policy formulation in regards to ensuring food safety.

(Definition)

Article 2

"Food" as used in this Law shall mean all food and drink (excluding drugs and quasi-drugs provided by the Pharmaceutical Affairs Law (Law No. 145 of 1960)).

(Basic recognition in taking measures for ensuring food safety)

Article 3

Food safety shall be ensured by taking necessary measures based on a basic recognition that the protection of nationals' health is of ultimate priority.

(Appropriate measures at each stage of the food supply process)

Article 4

In consideration that food safety may be affected by every element in a series of internal and external food supply processes from the production of agricultural, forestry and fishery products to food sales (hereinafter referred to as "food supply process"), food safety shall be ensured by taking the necessary measures appropriately at each stage of the food supply process.

(Prevention of adverse effect on nationals' health)

Article 5

Food safety shall be ensured by taking necessary measures on the basis of scientific knowledge and in sufficient consideration of international trends and nationals' opinions in respect of ensuring food safety, for the purpose of preventing an adverse effect on nationals' health due to food ingestion.

(Responsibilities of the state)

Article 6

The state shall be responsible for comprehensively formulating and implementing policies to ensure food safety on the code of basic principles for ensuring of food safety provided in the preceding three articles (hereinafter referred to as the "basic principles").

(Responsibilities of the local governments)

Article 7

The local governments shall be responsible for formulating and implementing policies to ensure food safety that corresponds to the natural, economic and social conditions of the area under their jurisdiction, on the code of the basic principles and on the basis of an appropriate sharing of roles with the state.

(Responsibility of food-related business operators)

Article 8

Business operators that produce, import, sell or conduct other business for fertilizers, agricultural chemicals, feed, feed additives, veterinary medicines and other production materials for agriculture, forestry or fishery that may have an effect on food safety, food (including agricultural, forestry and fishery products used as raw materials or materials), additives (those provided in Article 2, paragraph 2 of the Food Sanitation Law (Law No. 233 of 1947)), apparatuses (those provided in Article 2, paragraph 4 of the said Law) or containers and packages (those provided in Article 2, paragraph 5 of the said Law) (hereinafter referred to as "food-related business operators") shall be responsible for appropriately taking necessary measures to ensure food safety at each stage of the food supply process on the code of the basic principles and on the basis of the recognition that they bear the primary responsibility for ensuring food safety when conducting their business activities.

2. In addition to the provisions of the preceding paragraph, food-related business operators shall, in conducting their business activities, make efforts to provide accurate and appropriate information concerning food and other articles related to their own business activities on the code of the basic principles.

3. In addition to the provisions of the preceding two paragraphs, food-related business operators shall be responsible for cooperating in policies to ensure food safety which are implemented by the state or the local governments in respect of their business activities, on the code of the basic

principles.

(Roles of consumers)

Article 9

Consumers shall play an active role in ensuring food safety by endeavor to improve their own knowledge and understanding of the ensuring of food safety and by making efforts to express their opinions about policies to ensure food safety.

(Legislative measures, etc.)

Article 10

The government shall take legislative or financial measures and other measures that are necessary to implement policies to ensure food safety.

Chapter II Basic Directions for Policy Formulation

(Implementation of assessment of the effect of food on health)

Article 11

In formulating policies to ensure food safety, assessment shall be made for each policy on the effects that potentially harmful biological, chemical or physical agents in food or the condition of food have on human health, through the ingestion of the food (hereinafter referred to as the “assessment of the effect of food on health”), provided that this shall not apply to the following cases:

- (1) where the assessment of the effect of food on health is explicitly unnecessary in consideration of the contents of the measure;
 - (2) where the contents and degree of adverse effect on human health is clear;
 - (3) where there is no time to conduct the assessment of the effect of food on health in advance in cases where the measure is urgently necessary to prevent or control an adverse effect on human health.
2. In cases as cited in (3) of the preceding paragraph, the assessment of the effect of food on health shall be conducted subsequently and without delay.
3. The assessment of the effect of food on health provided in the preceding two paragraphs shall be conducted in an objective, neutral and fair manner on the basis of the state-of-the-art scientific knowledge of the time.

(Formulation of policies on the basis of the results of the assessment of the effect of food on health and in consideration of the conditions of nationals’ dietary habits and other circumstances)

Article 12

In formulating policies to ensure food safety, it shall be conducted for the purpose of preventing and restraining the adverse effect of food ingestion on human health in consideration of the conditions of nationals' dietary habits and other circumstances and on the basis of the results of the assessment of effect of food on health if conducted in accordance with the provisions of paragraph 1 or 2 of the preceding article.

(Promotion of exchanges of information and opinions)

Article 13

In formulating policies to ensure food safety, necessary measures for promoting the mutual exchanges of information and opinions among persons or parties concerned, such as provision of information concerning the policies and grant of opportunities to comment on the policies, shall be taken in order to reflect public opinions in the formulation of the policies and ensure the fairness and transparency of the process.

(Establishment of a system to cope with emergency situations, etc.)

Article 14

In formulating policies to ensure food safety, necessary measures, such as establishment of a system to cope with or prevent emergency situations that cause or are liable to cause serious damage to human health by food ingestion, shall be taken in order to prevent such damage.

(Close and mutual cooperation among related administrative bodies)

Article 15

In formulating policies to ensure food safety, close and mutual cooperation among related administrative bodies shall be made in order to make necessary measures for ensuring food safety to be appropriately taken at each stage of the food supply process.

(Establishment of research systems, etc.)

Article 16

In formulating policies to ensure food safety, necessary measures, such as establishment of research systems, promotion of research and development, dissemination of results thereof and training of researchers, shall be taken in consideration that efforts to improve scientific knowledge are important for ensuring food safety.

(Collection, arrangement and utilization of internal and external information, etc.)

Article 17

In formulating policies to ensure food safety, necessary measures, such as the collection,

arrangement and utilization of internal and external information about ensuring food safety, shall be taken in order to appropriately and effectively implement necessary measures for ensuring food safety in response to changes in the environment surrounding nationals' dietary habits.

(Ensuring the appropriate operation of a labeling system, etc)

Article 18

In formulating policies to ensure food safety, necessary measures for accurately conveying the information on food, such as ensuring the appropriate operation of a food labeling system, shall be taken in consideration that the food labeling plays an important role in ensuring food safety.

(Education and learning regarding ensuring food safety, etc)

Article 19

In formulating policies to ensure food safety, necessary measures for improving nationals' knowledge and understanding of ensuring food safety shall be taken by promoting education and learning and improving public relations activities on ensuring food safety.

(Consideration for effects on the environment)

Article 20

In formulating policies to ensure food safety, the effects of policies on the environment shall be considered.

(Determination and publication of Basic Matters concerning implementation of measures)

Article 21

The government shall determine basic matters concerning implementation of measures (hereinafter referred to as "Basic Matters") that are to be taken in accordance with the provisions of Articles 11 to 20.

2. The Prime Minister shall formulate a draft of Basic Matters after hearing the opinions of the Food Safety Commission and shall ask the Cabinet for its decision.

3. The Prime Minister shall promulgate the Basic Matters without delay when the Cabinet has made its decision in accordance with the provision of the preceding Paragraph.

4. The provisions of the preceding two paragraphs shall apply mutatis mutandis to the changes of the Basic Matters.

Chapter III Food Safety Commission

(Establishment)

Article 22

The Food Safety Commission (hereinafter referred to as the “Commission”) shall be established in the Cabinet Office.

(Office duties under the jurisdiction of the Commission)

Article 23

The Commission shall take charge of the following office duties:

- (1) to offer opinions to the Prime Minister in accordance with the provisions of Article 21, paragraph 2;
 - (2) to conduct the assessment of the effect of food on health in accordance with the provisions of the following article or at its direction;
 - (3) to make recommendations to related ministers through the Prime Minister about policies to be implemented for ensuring food safety on the basis of the results of the assessment of the effect of food on health, which was conducted in accordance with the provisions of the preceding item;
 - (4) to monitor the implementation conditions of policies that are implemented on the basis of the results of the assessment of the effect of food on health, which was conducted in accordance with the provisions of item (2), and to make recommendations to related ministers through the Prime Minister if necessary;
 - (5) to examine and deliberate on important matters regarding policies to be implemented for ensuring food safety, and to give opinions to the heads of related administrative bodies if necessary;
 - (6) to conduct scientific research and study necessary to perform office duties cited in items (2) to (5);
 - (7) to plan and implement the mutual exchange of information and opinions among persons or parties concerned in respect of office duties cited in items (2) to (6); and
 - (8) to coordinate office duties conducted by related administrative bodies regarding the mutual exchange of information and opinions among persons or parties concerned in respect to ensuring food safety.
2. When the Commission conducted the assessment of the effect of food on health in accordance with the provisions of (2) of the preceding paragraph, it shall notify related ministers of the results of the assessment without delay.
 3. When the Commission has given notification in accordance with the provisions of the preceding paragraph or made a recommendation in accordance with the provisions of (3) or (4) of paragraph 1, it shall publish the contents of the notification or the recommendation without delay.
 4. Related ministers shall report to the Commission on policies that they have implemented on the basis of a recommendation in accordance with the provisions of (3) or (4) of paragraph 1.

(Hearing of the Commission's opinions)

Article 24

In any of the following cases, related ministers shall hear the Commission's opinions, provided that this shall not apply to cases which the Commission recognizes as falling under Article 11, paragraph 1 (1) or which the related minister recognizes as falling under (3) of the same paragraph:

- (1) when intending to prescribe cases that are not injurious to human health as provided in the proviso of Article 4 (2) of the Food Sanitation Law (including cases where it applies *mutatis mutandis* in Article 29, paragraph 2 of the said Law), when intending to prohibit sales in accordance with the provisions of Article 4-2 of the said Law, when intending to enact, amend or abolish the Ministry of Health, Labour and Welfare Ordinance provided in Article 5, paragraph 1 of the said Law, when intending to prescribe cases that are not injurious to human health as provided in Article 6 of the said Law, when intending to establish standards or specifications in accordance with the provisions of Article 7, paragraph 1 of the said Law (including cases where it applies *mutatis mutandis* in Article 29, paragraph 2 of the said Law) or Article 10, paragraph 1 of the said Law (including cases where it applies *mutatis mutandis* in Article 29, paragraph 3 of the said Law), or when intending to establish standards in accordance with the provisions of Article 19-18, paragraph 1 of the said Law;
- (2) when intending to set, change or abolish official specifications in accordance with the provisions of Article 1-3 of the Agricultural Chemicals Regulation Law (Law No. 82 of 1948), when intending to designate or change the designation of specified agricultural chemicals in accordance with the provisions of Article 2, paragraph 1 of the said Law, or when intending to establish or change the standards (excluding standards for determining whether falling under cases cited in Article 3, paragraph 1 (6) or (7) of the said Law) provided in Article 3, paragraph 2 of the said Law (including cases where it applies *mutatis mutandis* in Article 15-2, paragraph 6 of the said Law);
- (3) when intending to set, change or abolish official specifications in accordance with the provisions of Article 3 of the Fertilizer Control Law (Law No. 127 of 1950);
- (4) when intending to form a plan for enactment, amendment or abolishment of the Cabinet Order provided in Article 2, paragraph 1 of the Domestic Animal Infectious Disease Control Law (Law No. 166 of 1951), when intending to enact, amend or abolish the Ministry of Agriculture, Forestry and Fisheries Ordinance, which prescribes reported communicable diseases referred to in Article 4, paragraph 1 of the said Law, or when intending to form a plan for enactment, amendment or abolishment of the Cabinet Order provided in Article 62 of the said Law;
- (5) when intending to designate feed additives in accordance with the provisions of Article 2, paragraph 3 of the Law Concerning Safety Assurance and Quality Improvement of Feed (Law No.

35 of 1953), when intending to establish, amend or abolish standards or specifications in accordance with the provisions of Article 2-2, paragraph 1 of the said Law, or when intending to prohibit sales in accordance with the provisions of Article 2-6 of the said Law;

(6) when intending to enact, amend or abolish the Ministry of Health, Labour and Welfare Ordinance provided in Article 9, paragraph 1 (3) of the Abattoirs Law (Law No. 114 of 1953), or when intending to form a plan for enactment, amendment or abolishment of the Cabinet Order provided in Article 10, paragraph 5 of the said Law;

(7) when intending to enact, amend or abolish the Ministry of Health, Labour and Welfare Ordinance provided in Article 4, paragraph 2 (limited to the part pertaining to the provisions of paragraph 1 (1) to (3) of the said article) of the Waterworks Law (Law No. 177 of 1957);

(8) when intending to give approval for drugs, quasi-drugs or medical devices for the purpose of use for animals (hereinafter referred to as "veterinary medicine, etc.") in accordance with the provisions of Article 14, paragraph 1 of the Pharmaceutical Affairs Law (including cases where it applies *mutatis mutandis* in Article 23 of the said Law; the same shall apply hereunder) or the provisions of the said paragraph applied in accordance with the provisions of Article 83 of the said Law, when intending to conduct a re-examination of veterinary medicine, etc. in accordance with the provisions of Article 14-4, paragraph 1 of the said Law (including cases where it applies *mutatis mutandis* in Article 19-4 and Article 23; the same shall apply hereunder) or the provisions of the said paragraph applied in accordance with the provisions of Article 83 of the said Law, when intending to conduct re-assessment of veterinary medicine, etc. in accordance with the provisions of Article 14-5, paragraph 1 of the said Law (including cases where it applies *mutatis mutandis* in Article 19-4 and Article 23 of the said Law; the same shall apply hereunder) or the provisions of the said paragraph applied in accordance with the provisions of Article 83 of the said Law, when intending to give approval for veterinary medicine, etc. in accordance with the provisions of Article 19-2, paragraph 1 of the said Law or the provisions of the said paragraph applied in accordance with the provisions of Article 83 of the said Law, or when intending to enact, amend or abolish the Ministry of Agriculture, Forestry and Fisheries Ordinance provided in Article 83-2, paragraph 1 of the said Law;

(9) when intending to form a plan for the enactment, amendment or abolishment of the Cabinet Order (limited to those that designate substances contained in agricultural land soil, which are feared to become the source of the production of agricultural crops, and livestock that are feared to be harmful to human health) provided in Article 2, paragraph 3 of the Agricultural Land Soil Pollution Prevention Law (Law No. 139 of 1970) or the Cabinet Order provided in Article 3, paragraph 1 of the said Law (limited to those that prescribe conditions for areas where the agricultural lands are understood to be used for the production of agricultural crops and livestock that are feared to be harmful to human health or where the fear thereof is understood to be

conspicuous);

(10) when intending to enact, amend or abolish the Ministry of Health, Labour and Welfare Ordinance provided in Article 11, Article 15, paragraph 5 or Article 19 of the Poultry Slaughtering Business Control and Poultry Meat Inspection Law (Law No. 70 of 1990);

(11) when intending to form a plan for enactment, amendment or abolishment of the Cabinet Order provided in Article 6, paragraph 1 of the Law Concerning Special Measures against Dioxins (Law No. 105 of 1999);

(12) when intending to enact, amend or abolish the Ministry of Health, Labour and Welfare Ordinance provided in Article 7, paragraph 1 or 2 of the Law concerning Special Measures against Bovine Spongiform Encephalopathy (Law No. 70 of 2002); and

(13) in addition to those cited in the preceding items, cases provided by the Cabinet Order.

2. In cases falling under the proviso of the preceding paragraph (limited to cases recognized by the related ministers as falling under Article 11, paragraph 1 (3)), related ministers shall report such fact to the Commission and hear its opinions within a certain period of time after the formulation of policies to ensure the safety of the food,.

3. In addition to cases provided in paragraph 1, related ministers may hear the Commission's opinions if they are recognized as necessary for formulating policies to ensure food safety.

(Request for submission of materials, etc.)

Article 25

The Commission may request that the heads of related administrative bodies submit materials, opinions, and explanations and provide other necessary cooperation, if it is recognized to be necessary for performing office duties under its jurisdiction.

(Entrustment of investigation)

Article 26

The Commission may entrust necessary investigations to incorporated administrative agencies, juristic persons incorporated in accordance with the provisions of Article 34 of the Civil Code of Japan (Law No. 89 of 1896), enterprises and other private bodies, prefectural experiment and research institutes, or persons of learning and experience, if it is recognized to be necessary for performing office duties under its jurisdiction.

(Request in an emergency)

Article 27

The Commission may request that the research institutes of related national administrative bodies conduct an investigation, analysis or examination necessary for the assessment of the effect of food

on health if it is recognized to be necessary for coping with emergency situations that cause or are liable to cause serious damage concerning ensuring food safety.

2. If the research institutes of related national administrative bodies receive a request from the Commission in accordance with the provisions of the preceding paragraph, they shall promptly implement the requested research, analysis or examination.

3. The Commission may request that related ministers make a demand in accordance with the provisions of Article 12, paragraph 1 of the Incorporated Administrative Agency, National Institute of Health and Nutrition Law (Law No. 180 of 1999) or a request in accordance with the provisions of Article 12, paragraph 1 of the Incorporated Administrative Agency, Center for Food Quality, Labeling and Consumer Services Law (Law No. 183 of 1999), Article 12, paragraph 1 of the Incorporated Administrative Agency, National Agricultural Research Organization Law (Law No. 192 of 1999), Article 12, paragraph 1 of the Incorporated Administrative Agency, National Institute for Agro-Environmental Sciences Law (Law No. 194 of 1999), Article 12, paragraph 1 of the Incorporated Administrative Agency, National Food Research Institute Law (Law No. 196 of 1999), or Article 12, paragraph 1 of the Incorporated Administrative Agency, Fisheries Research Agency Law (Law No. 199 of 1999), if it is recognized to be necessary for coping with emergency situations that cause or are liable to cause serious damage to the ensuring of food safety.

(Organization)

Article 28

The Commission shall be organized by seven commission members.

2. Three out of the seven Commission Members shall be part-time members.

(Appointment of Commission Members)

Article 29

With approval from both Houses, the Prime Minister shall appoint Commission Members out of those who have superior insight into ensuring food safety.

2. In spite of the provisions of the preceding paragraph, the Prime Minister may appoint Commission Members out of those who have qualifications as provided in the preceding paragraph, if he/she cannot obtain approval on the appointment from both Houses due to the Diet's closing or the dissolution of the House of Representatives in cases where the term of the Commission Members has expired or there arises a vacancy for a Commission Member.

3. In cases falling under the preceding paragraph, the Prime Minister shall obtain subsequent approval from both Houses at the first Diet session after the relevant appointment. If the Prime Minister cannot obtain subsequent approval from both Houses in such case, the Prime Minister shall immediately dismiss the Commission Member.

(Term of the Commission Member)

Article 30

The term of the Commission Member shall be three years, provided that the term of a substitute Commission Member shall be the remaining term of his/her predecessor.

2. The Commission Member may be reappointed.
3. If the term of the Commission Member has expired, the relevant Commission Member shall perform his/her duties until his/her successor is appointed.

(Dismissal of the Commission Member)

Article 31

With approval from both Houses, the Prime Minister may dismiss the Commission Member if the Commission member is recognized as being incapable of performing his/her duties due to physical or mental disability or if recognized as constituting a violation of his/her official obligations or other delinquency inappropriate for a Commission Member.

(Service of the Commission Member)

Article 32

The Commission Member shall not disclose secrets that he/she has come to know through his/her duties. The same shall apply even after he/she leaves the office.

2. The Commission Member, while in office, shall not serve as an officer of a political party or other political association or actively take part in political movements.
3. The full-time Commission Member, while in office, shall not engage in another job for remuneration, run a commercial enterprise, or conduct any other business for the purpose of financially gain except where they have received the Prime Minister's permission.

(Allowance of the Commission Member)

Article 33

The salary of the Commission Member shall be provided by separate law.

(Chairperson)

Article 34

The position of Chairperson shall be established in the Commission and the Chairperson shall be appointed from full-time Committee Members by a mutual vote among the Commission Members.

2. The Chairman shall administrate the duties of the Commission and shall represent the Commission.

3. In the event that the Chairperson has an accident, the full-time Commission Member who has been designated in advance by the Chairperson shall perform the duties of the Chairperson.

(Meeting)

Article 35

The Commission shall be assembled by the Chairperson.

2. The Commission shall not hold a meeting and make a decision without the attendance of the Chairperson and at least three Commission Members.

3. The proceedings of the Commission shall be determined by the majority of attendees, and in cases in which the Commission is evenly divided, it shall be as determined by the Chairperson.

4. In respect of the application of the provisions of paragraph 2 about cases where the Chairperson is in an accident, the Committee Member provided in paragraph 3 of the preceding article shall be deemed to be the Chairperson.

(Expert Commission Member)

Article 36

The Commission may have the Expert Commission Member examine and deliberate on specialized matters.

2. The Prime Minister shall appoint the Expert Commission Member from persons of learning and experience.

3. The Expert Commission Member shall be dismissed at the completion of the examination and deliberation of the relevant specialized matters.

4. The Expert Commission Member shall be on part-time basis.

(Secretariat)

Article 37

The Commission shall establish the Secretariat to deal with clerical work.

2. The Secretariat shall have the necessary officials as well as the Secretary-General.

3. The Secretary-General shall administer the duties of the Secretariat at the behest of the Chairperson.

(Delegation to Cabinet Order)

Article 38

In addition to matters provided in this Chapter, necessary matters regarding the Commission shall be provided by Cabinet Order.

Nutrition Labeling Standards

Those who wish to make a claim about energy or a particular nutrient under the Health Promotion Law must observe the following requirements:

In general

1. Target items

In all cases, the nutrients given in A through E below must be indicated. If one or more of the nutrients given in F are claimed, the corresponding nutrients must be indicated. Indication must be in the order listed below.

- A. Calorie
- B. Protein
- C. Fat
- D. Carbohydrates (or sugars and dietary fibers)
- E. Sodium
- F. Others

Minerals: Calcium, Iron, Potassium, Phosphorus, Magnesium, Zinc, Copper, Manganese, Iodine, Selenium, Chrome.

Vitamins: Vitamin A, Vitamin B₁, Vitamin B₂, Vitamin B₆, Vitamin B₁₂, Niacin, Vitamin C, Vitamin D, Vitamin E, Vitamin K, Folic acid, Pantothenic acid, Biotin.

2. The information must be written in Japanese on its container or package in a manner that is easily readable without opening the container or package.

3. The amount of each nutrient must be indicated per 100g or 100ml, or per serving, per package, or per other appropriate unit. The amount must be expressed in the corresponding unit below.

- A. Calorie: kilocalorie (kcal).
- B. Protein: gram (g).
- C. Fat: gram (g).
- D. Carbohydrates: gram (g).
- E. Minerals

Calcium, Iron, and Sodium: milligram(mg).

If 1,000 mg or more of sodium is indicated, gram (g) can be used.

F. Vitamins

Vitamin A and Vitamin D: microgram (μg) or international unit (IU).

Niacin, Pantothenic acid, Vitamin B₁, Vitamin B₂, Vitamin B₆, Vitamin C, and Vitamin E: milligram (mg).

Biotin, Vitamin B₁₂, and Folic acid: microgram (μg).

4. When the amount of a nutrient is indicated as being a certain level, the actual level obtained using the specified method must be within the following range:

Calorie, Protein, Fat, Saturated fatty acid, Cholesterol, Carbohydrate, Sugars, Dietary fiber, and Sodium: $\pm 20\%$

Vitamin A, Vitamin D, Vitamin E, Calcium, and Iron: -20% to $+50\%$

Vitamin B₁, Vitamin B₂, Vitamin B₆, Vitamin B₁₂, Vitamin C, Niacin, Pantothenic acid, Biotin, and Folic acid: -20% to $+80\%$

5. When the amount is indicated with upper and lower limits, the actual level obtained using specified method must be within the labeled range.

Claim using the term "high," "source of," or "fortified"

Target nutrients: Protein, Dietary fibers, Calcium, Iron, Niacin, Pantothenic acid, Biotin, Vitamin A, Vitamin B₁, Vitamin B₂, Vitamin B₆, Vitamin B₁₂, Vitamin C, Vitamin D, Vitamin E, and Folic acid.

For the above-mentioned target nutrients:

- A. A food bearing the claim "high" or "rich" must contain the given level or more of the nutrient (see Table 1).
B. A food bearing the claim "source of a nutrient" or "containing a nutrient" must contain the given level or more of the nutrient (see Table 2).

For the above-mentioned target nutrients, a food bearing the claim that a specific nutrient is fortified to a certain level as compared with the reference food must satisfy the following requirements:

- A. The reference food must be indicated, and
B. The fortified level must be the given level or more (see Table 2).

Claim using the term "non," "free" or "zero," or "low" or "reduced"

Target nutrients: Calorie, Fat, Saturated fatty acid, Cholesterol, Sugars

(monosaccharides and disaccharides only, except sugar alcohols),
and Sodium.

For the above-mentioned target nutrients:

- A. A food bearing the claim “non,” “free,” or “zero” must contain the given level or less of the nutrient (see Table 3).
- B. A food bearing the claim “low” or “light” must contain the given level or less of the nutrient (see Table 4).

For the above-mentioned target nutrients, a food bearing the claim that a specific nutrient is reduced by a certain level as compared with the reference food must satisfy the following requirements:

- A. The reference food must be indicated, and
- B. The reduced level must be the given level or more (see Table 4)

Claim using the expression “reduced-sodium soy sauce”

For soy sauce bearing the claim “reduced sodium,” sodium must be reduced by 20% or more as compared with ordinary products.

Table 1. Claim using the term, "high" or "rich"

Nutrient	Minimum level
Protein	12 g/100 g (solid), 6 g/100ml (liquid), 6 g/100kcal
Dietary fiber	6 g/100 g (solid), 3 g/100ml (liquid), 3 g/100kcal
Calcium	210 mg/100 g (solid), 105 mg/100 ml (liquid), 70 mg/100 kcal
Iron	3.6 mg/100 g (solid), 1.8 mg/100 ml (liquid), 1.2 mg/100 kcal
Niacin	4.5 mg/100 g (solid), 2.3 mg/100 ml (liquid), 1.5 mg/100 kcal
Pantothenic acid	1.50 g/100 g (solid), 0.75 g/100 ml (liquid), 0.50 g/100 kcal
Biotin	9.0 µg/100 g (solid), 4.5 µg/100ml (liquid), 3.0 µg/100 kcal
Vitamin A	162 µg/100 g (solid), 81 µg/100 ml (liquid), 54 µg/100 kcal
Vitamin B ₁	0.30 mg/100 g (solid), 0.15 mg/100 ml (liquid), 0.10 mg/100 kcal
Vitamin B ₂	0.33 mg/100 g (solid), 0.17 mg/100 ml (liquid), 0.11 mg/100 kcal
Vitamin B ₆	0.45 mg/100g (solid), 0.23 mg/100 ml (liquid), 0.15 mg/100 kcal
Vitamin B ₁₂	0.72 µg/100 g (solid), 0.36 µg/100 ml (liquid), 0.24 µg/100 kcal
Vitamin C	30 mg/100 g (solid), 15 mg/100 ml (liquid), 10 mg/100 kcal
Vitamin D	0.75 µg/100 g (solid), 0.38 µg/100 ml (liquid), 0.25 µg/100 kcal
Vitamin E	3.0 mg/100 g (solid), 1.5 mg/100 ml (liquid), 1.0 mg/100 kcal
Folic acid	60 µg/100 g (solid), 30 µg/100 ml (liquid), 20 µg/100 kcal

Table 2. Claim using the term, “containing” or “source of,” or “fortified”

Nutrient	Minimum level
Protein	6 g/100 g (solid), 3 g/100ml (liquid), 3 g/100 kcal
Dietary fiber	3 g/100 g (solid), 1.5 g/100 ml (liquid), 1.5 g/100 kcal
Calcium	105 mg/100 g (solid), 53 mg/100 ml (liquid), 35 mg/100 kcal
Iron	1.8 mg/100 g (solid), 0.9 mg/100 ml (liquid), 0.6 mg/100 kcal
Niacin	2.3 mg/100 g (solid), 1.1 mg/100 ml (liquid), 0.8 mg/100 kcal
Pantothenic acid	0.75 g/100 g (solid), 0.38 g/100 ml (liquid), 0.25 g/100 kcal
Biotin	4.5 µg/100 g (solid), 2.3 µg/100 ml (liquid), 1.5 µg/100 kcal
Vitamin A	81 µg/100 g (solid), 41 µg/100 ml (liquid), 27 µg/100 kcal
Vitamin B ₁	0.15 mg/100 g (solid), 0.08 mg/100 ml (liquid), 0.05 mg/100 kcal
Vitamin B ₂	0.17 mg/100 g (solid), 0.09 mg/100 ml (liquid), 0.06 mg/100 kcal
Vitamin B ₆	0.23 mg/100 g (solid), 0.11 mg/100 ml (liquid), 0.08 mg/100 kcal
Vitamin B ₁₂	0.36 µg/100 g (solid), 0.18 µg/100 ml (liquid), 0.12 µg/100 kcal
Vitamin C	15mg/100g (solid), 8mg/100ml (liquid), 5mg/100kcal
Vitamin D	0.38 µg/100 g (solid), 0.19 µg/100 ml (liquid), 0.13 µg/100 kcal
Vitamin E	1.5 mg/100 g (solid), 0.8 mg/100 ml (liquid), 0.5 mg/100 kcal
Folic acid	30 µg/100 g (solid), 15 µg/100 ml (liquid), 10 µg/100 kcal

Table 3. Claim using the term, "free," "zero," or "non"

Item	Maximum level
Energy	5 kcal/100 g or 100 ml
Fat	0.5 g/100 g or 100 ml
Saturated fatty acid	0.1 g/100 g or 100 ml
Cholesterol	5 mg/100 g or 100 ml*, 1.5 g saturated fatty acid/100 g (solid) or 0.75 g saturated fatty acid/100 ml (liquid), and Energy derived from saturated fatty acid: 10% of the total energy
Sugars	0.5 g/100 g or 100 ml
Sodium	5 mg/100 g or 100 ml

Table 4. Claim using the term, "low," "light" or "less," or "reduced" or "cut off"

Item	Maximum level (or reduced level)
Energy	40 kcal/100 g (solid) or 20 kcal/100 ml (liquid)
Fat	3 g/100 g (solid) or 1.5 g/100 ml (liquid)
Saturated fatty acid	1.5 g/100 g (solid) or 0.75 g/100 ml (liquid) and Energy derived from saturated fatty acid: 10% of the total energy
Cholesterol	20 mg/100 g (solid) or 10 mg/100 ml (liquid) 1.5 g saturated fatty acid/100 g (solid) or 0.75 g saturated fatty acid/100 ml (liquid), and Energy derived from saturated fatty acid: 10% of the total energy
Sugars	5 g/100 g (solid) or 2.5 mg/100 ml (liquid)
Sodium	120 mg/100 g or 100 ml

Note: This requirement does not apply to a food for which the single serving size is 15g or less and in which saturated fatty acid accounts for 15% or less of the total fatty acid.

**List of reference materials acquired from the visit and related information
which the delegation has considered in drawing up its observations**

Publications

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- ***Food Sanitation Law***
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- ***Kinki Regional Bureau of Health and Welfare - 2003 Guide*** / Ministry of Health, Labour and Welfare / 2003
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- **市場のしなり Market Guide** / Map of locations of Tokyo Metropolitan Central Wholesale Market
- ***The Present Status of Imported Food at Narita Airport, 2002*** / Food Inspection Division, Narita Airport Quarantine Station, Ministry of Health, Labour and Welfare / 2002
- ***Yokohama Quarantine Station*** / Ministry of Health, Labour and Welfare / January 2004
- ***Examination Center*** / Yokohama Quarantine Station, Ministry of Health, Labour and Welfare
- **千代田区「生活環境條例」のあらまし**
- ***Genetically Modified Food Labelling (RP05/02-03)*** / Research and Library Services Division, Legislative Council Secretariat / 19 March 2003
- ***Information note on "Health regulations for the import of food in Japan and the export of food in Australia" (IN 32/01-02)*** / Research and Library Services Division, Legislative Council Secretariat / 9 July 2002

Websites

Ministry of Health, Labour and Welfare

<http://www.mhlw.go.jp>

Ministry of Agriculture, Forestry and Fisheries

<http://www.maff.go.jp>

Kinki Regional Bureau of Health and Welfare

<http://www.hosp.go.jp/~kinki/>

Food Safety Commission

<http://www8.cao.go.jp/shokuhin>

Chiyoda Ward

<http://www.poisute.com>